

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT / APPLICANT: Eric B. STENZEL
SERIAL NO.: 10/701,455
FILED: November 6, 2003
FOR: METHOD AND APPARATUS FOR CONTROLLED
DELIVERY OF ACTIVE SUBSTANCE
ART UNIT: 3738
EXAMINER: Gherbi, Suzette J. J.

COMMISSIONER FOR PATENTS
P. O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

In accordance with 37 C.F.R. § 41.41, the Appellant respectfully submits this Reply Brief, in triplicate, in reply to the Examiner's Answer dated December 19, 2006.

Argument

Rejection Under 35 U.S.C. § 112

In the Examiner's Answer, the Examiner has withdrawn the rejection of the claims under 35 U.S.C. § 112, first paragraph. Accordingly, the Appellant's appeal of that rejection is now rendered moot.

Objection to the Drawings

In the Final Office Action dated September 23, 2005, the drawings were objected to under 37 C.F.R. § 1.83(a). That Appellant has previously pointed out that the objection to the drawings appeared to be based on the rejection under 35 U.S.C. § 112, first paragraph, and that

reversal of the rejection under 35 U.S.C. § 112 would render moot the objection to the drawings. (See Appeal Brief, 9/13/06, pp. 20-21). In the Examiner's Answer, the Examiner withdrew the rejection under 35 U.S.C. § 112, first paragraph, but the Examiner did not address the objection to the drawings. It is the Appellant's understanding that, due to the withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, there is no longer an objection to the drawings.

Rejections Under 35 U.S.C. § 103(a)

In the Appellant's Appeal Brief, the Appellant pointed out that the Appellant's invention as claimed in the claims on appeal involves having micro-coated pellets wherein a first set of coated pellets has a different dissolution rate from a second set of coated pellets because they have different coating thicknesses, yet, despite different coating thicknesses, the first and second coated pellets have "**substantially the same size.**" This is accomplished by having an additional substance inside the coated pellets with the thinner coatings, the additional substance filling the volume to make up for the thinner coating. (See Appeal Brief, 9/13/06, pp. 4-7, 13-14). The Appellant pointed out that Figure 7 of the Stoll '089 patent shows microcapsules having **different** sizes. The Appellant pointed out that there was no teaching, suggestion or motivation in the prior art for modifying the Stoll Figure 7 device to have coated pellets with "substantially the same size" as required by each of Appellant's claims. (See Appeal Brief, 9/13/06, pp. 13-16).

In the Examiner's Answer, the Examiner nowhere mentions the claim limitation that the coated pellets must be "substantially the same size." The Examiner does not explain how the proposed rejection under 35 U.S.C. § 103 supposedly results in the Stoll Figure 7 device having coated pellets with "substantially the same size."

The only possible intimation regarding this claim limitation that the Appellant can glean from the Examiner's Answer is its parenthetical statement that "(the pellet is the internal

structure 4" and the coating is the thin surrounding)." Perhaps the Examiner is meaning to say that the "coated pellet" as claimed corresponds only to the internal material 4" in Stoll Figure 7 and not to the entire coated microcapsule 5". In this way, perhaps the Examiner is meaning to say that the pellets in Stoll Figure 7 have "substantially the same size" because the internal material 4" inside each of the microcapsules has substantially the same size. That is, perhaps the Examiner is pointing out that it is just the coating thicknesses that differ between different Stoll microcapsules, and that, according to the Examiner the "coated pellet" is just what is inside the coating.

It is not at all clear that this is actually what the Examiner is arguing. In the Office Action dated December 23, 2005, the Examiner equated the claimed "coated pellet" with the entire Stoll microcapsule, i.e., including the coating. For example, the Examiner at that time said that Stoll has "a set of first coated pellets (the coating is 5")," indicating that the coating in Stoll was considered part of the coated pellet. (See Office Action, 12/23/05, p. 4). The Examiner also at that time said that "the round sphere micro-capsules [of Stoll] equate to the claimed pellet," and the Stoll micro-capsules include the coating. Id.

Nevertheless, if the Examiner intends now to argue that only what is inside the Stoll micro-capsules corresponds to the claimed "coated pellet," that argument is flawed. The claims require that the coated pellets, not the uncoated pellets, must be substantially the same size. Claim 1 says that "each of the first coated pellets is substantially the same size as each of said second coated pellets." Claim 12 says that "each of said first coated pellets is substantially the same size as each of said second coated pellets." Claim 17 defines the "pellets" as "comprising a therapeutic composition and a protective layer" and says that "each of said first and second pellets is substantially the same size." The sizes that are being compared are the sizes of the

entire coated pellets – i.e., including the coatings or protective layers. This is required by the plain language of the claims.

Claims 1 and 12 both say “coated pellets.” That term refers to the entire coated pellet including the coating, not just what is inside the coating. Claim 17, while not expressly saying “coated pellet,” is nevertheless similarly clear. Claim 17 defines the first pellets as “comprising a therapeutic composition and a protective layer.” Claim 17 also defines the second pellets as “comprising a therapeutic composition and a protective layer.” Then, claim 17 states that “each of said first and second pellets is substantially the same size.” Since the pellets “comprise,” i.e., include, the protective layer, it necessarily follows that the first pellets inclusive of the protective layer must be substantially the same size as the second pellets inclusive of the protective layer.

The Appellants respectfully submit that the prior art does not provide any teaching, suggestion or motivation for coated pellets wherein the coated pellets have different coating thicknesses yet substantially the same size. The Appellants respectfully refer to the Appeal Brief filed September 13, 2006, for further arguments supporting reversal of the rejections.

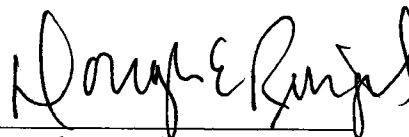
Conclusion

For the foregoing reasons, the Appellant respectfully requests reversal of the rejections of all pending claims.

The Office is hereby authorized to charge any additional fees under 37 C.F.R. §1.16 or §1.17 or credit any overpayment to Deposit Account No. 11-0600.

Respectfully submitted,

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Douglas E. Ringel
Registration No. 34,416

KENYON & KENYON LLP
1500 K Street, N.W., Suite 700
Washington, D.C. 20005-1257
Tel.: (202) 220-4200
Fax.: (202) 220-4201

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